LIBERTY IRB, Inc.
A CENTRAL INDEPENDENT REVIEW BOARD

Request for Determination of Exemption

This request form should be used if you wish to obtain a written opinion that a proposed project is exempt from the requirement for IRB review **or** does not require IRB review because the project does not involve research **or** does not involve human subjects.

Please submit the completed form together with the following:

- A copy of the protocol or a detailed description of the research;
- Copies of all data collection tools including case report forms and surveys; and
- Signed Submission letter requesting exemption
- Signed and dated curriculum vitae
- Medical license (if applicable)

There is no expiration date on its IRB exemption determinations; however, any future changes to the project may affect its exempt status. You should contact Liberty IRB regarding these changes before implementing them.

If this research will be conducted by a covered entity and involves the use and/or disclosure of protected health information (PHI), an authorization or waiver of authorization for the use/disclosure of the PHI might be required.

- Section I of this form asks for general information about the investigator and research staff.
- Sections II and III of this form ask for general information that would exclude the project from an exemption determination. **If you are unable to provide the requested confirmations for Sections II and III, the research would not be exempt.**
- Section IV of this form asks for information to determine if the research is exempt under the categories of exempt research found at 45 CFR 46(b). If you wish to obtain an opinion that you are doing research, it does involve human subjects, but that it should be exempt under these categories, you should complete Section IV of the request form.
- Section V of this form asks for information to determine if the activity is research. The regulations outlining the requirement for IRB review applies to research involving human subjects. **If you wish to obtain an opinion that your**

project does not involve research, you should complete Section V of the request form.

- Sections VI and VII of this form ask for information to determine whether the activity is research that does not involve human subjects. **If you wish to obtain an opinion that your project does not involve human subjects, you should complete Section VI or VII of the request form.**

Request for Determination of Exemption

Sponsor _____

Section I Principal Investigator (PI) Information: Please provide information about the person legally responsible for the conduct of the research.

1.	PI Name:		
2.	PI Company Name:		
3.	PI Mailing Address: (street, city, state/province, zip, country)		
4.	PI Phone: ( )	PI Fax: ( )	PI E-mail:
5.	Preferred method of contact: (mark one) _____Fax _____E-mail _____Regular Mail		

Other contact information:

6.	Study Coordinator or Other Contact Person Name:		
7.	Study Coordinator / Other Contact Person Phone: ( )	Study Coordinator / Other Contact Person Fax: ( )	Study Coordinator / Other Contact Person E-mail:
8.	Study Coordinator's/ Other Contact Person's preferred method of contact: (mark one) _____Fax _____ E-mail		

9.	Title of research project:
10.	Study is: _____ Single Center _____ Multi-center _____ You are the PI of the multi-center trial

Section II Please confirm that this investigation does not involve research on an FDA regulated product such as a drug or device. Exemption determinations for investigations of products regulated by the FDA except for taste and food quality evaluation and/or consumer acceptance studies cannot be granted. (Category 6 of Section IV below).

Section III Please confirm that you do not intend to include prisoners in this research. If prisoners will be included, the research is not exempt under federal regulation 45 CFR 46.101(b).

Section IV Categories of Exemption under 45 CFR 46.101(b)

The categories of exempt research are found at federal regulation 45 CFR 46.101(b). This regulation is included at the end of this request form. Please review the requirements and answer the questions below that relate to the exemption category most appropriate for your research.

	Category 1: 45 CFR 46.101(b)(1) ☐ NA		
1.	Will this research involve normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods? *If yes, please explain why you believe this research involves normal educational practices:	*Yes ☐	No ☐
2.	Please also explain why you believe this research will be conducted in an established or commonly accepted educational setting:		

	Category 2 and 3: 45 CFR 46.101(b)(2 and 3) _____ NA		
1.	Place an "X" by the following statements that are true: _____ The research involves educational tests (cognitive, diagnostic, aptitude, achievement) _____The research involves survey procedures* _____The research involves interview procedures* _____The research involves observation of public behavior* *If the research involves children, the exemption for this category is limited to educational tests and observation of public behavior where the investigator(s) will NOT participate in the activities being observed.		
2.	Will this project include children as research subjects? *If the research does involve children, the exemption for this category is limited to educational tests and observation of public behavior where the investigator(s) will NOT participate in the activities being observed.	*Yes ☐	No ☐

3.	Will the information obtained be recorded in such a manner that participants CANNOT be identified directly or through identifiers linked to the participants? *If no, please answer the next question under this category (3a).	Yes ☐	*No ☐
3a.	If the information would be recorded in such a manner that subjects can be identified directly, or through identifiers linked to the subjects, would any disclosure of the participants' responses outside the research reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability or reputation? . *If yes, the research is not exempt.	*Yes ☐	No ☐
4.	Are all of subjects of the research either elected or appointed public officials or candidates for public office?	Yes	No
5.	Does a federal statute require without exception that the confidentiality of personally identifiable information be maintained throughout the research and thereafter? *If yes, please provide a citation to the federal statute.	*Yes ☐	No ☐

Category 4: 45 CFR 46.101(b)(4)		_____ NA	
1.	Does the research involve the use of data, documents, records, pathological specimens, or diagnostic specimens that are currently existing (not being prospectively collected)?	Yes	No
2.	Are these documents or specimens publicly available?	Yes	No
3.	Will the investigator record any information in a manner such that subjects can be identified either directly or through identifiers linked to the subjects?	Yes	No

Category 5: 45 CFR 46.101(b)(5)		_____ NA	
1.	Is this research being conducted by a federal Department or Agency head?	Yes	No
2.	Has the research been approved by a federal Department or Agency head? *If yes, please provide documentation of approval.	*Yes	No
3.	Please place an "X" by the following statements that are true: _____ This project is designed to study, evaluate or otherwise examine a federal public benefit or service program. _____ This project is designed to study, evaluate or otherwise examine procedures for obtaining benefits or services under a federal public benefit program. _____ This project is designed to study, evaluate or otherwise examine possible changes in or alternatives to a federal public benefit or service program or procedures used by the program. _____ This project is designed to study, evaluate or otherwise examine possible changes in methods or levels of payment for benefits or services under a federal public benefit or service program.		
4.	The program being studied must deliver a public benefit program or service. Please describe the program or service being studied.		
5.	Is there a statutory requirement for IRB review of research on this benefit program? *If yes, then this research is not exempt.	*Yes	No

	Category 6: 45 CFR 46.101(b)(6)		_____NA
1.	Does this research involve a taste and food quality evaluation and/or consumer acceptance studies?	Yes ☐	No ☐
2.	Please place an "X" by the following statements that are true: _____Only wholesome foods without additives will be consumed. _____The food consumed will contain a food ingredient that is at or below the level found to be safe and is for a use found to be safe. _____ A food will be consumed that contains an agricultural chemical or environmental contaminant that is at or below the level found to be safe by the Food and Drug Administration. _____A food will be consumed that contains an agricultural chemical or environmental contaminant that is at or below the level approved by the Environmental Protection Agency. _____A food will be consumed that contains an agricultural chemical or environmental contaminant that is at or below the level approved by the Food Safety and Inspection Service of the Department of Agriculture.		

Section V Projects that do not involve research			
1.	Is the project a systematic investigation designed to develop or contribute to generalizable knowledge? *If no, please provide an explanation of why the project is not research under the definition above.	Yes ☐	*No ☐

Section VI Projects not involving human subjects			
1.	Does the project involve any intervention or interaction with a living individual?	Yes ☐	No ☐
2.	Does the project involve obtaining information about living individuals?	Yes ☐	No ☐

3.	Will the information obtained include any of the following? a. _____ Information about behavior that occurs in a situation in which an individual can reasonably expect that no observation or recording is taking place. b. _____Information provided for specific purposes by an individual in a setting in which the individual could reasonably expect the information would not be made public. c. _____ No, no information will be collected that fits into boxes a and b above.

Section VII Projects not involving human subjects because anonymous or coded samples will be used (based on the OHRP guidance of the same title)			
1.	Does the project involve obtaining biological samples from living individuals?	Yes	No
2.	Was the information or samples collected specifically for this project or were they collected for another purpose? _____They were collected for this project. _____They were collected for another purpose.		
3.	Will the investigator be able to discover the identity of the individual?	Yes	No

4.	Will the information or samples include any codes with links to the identity of the individual? *If yes, place an "X" by the following statements that are true (**at least one must be selected**): _____The key to decipher the code will be destroyed before the research begins. _____There is an agreement between the investigator and the holder of the key that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased. _____There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; _____There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased. _____Other (specify):_____	*Yes ☐	No ☐

NAME OF PERSON COMPLETING THIS FORM:

_____ _____
Printed or Typed Name of Person Completing This Form | Company & title

(_____)_____ (_____)_____ _____
Phone number | Fax number | E-mail address (optional)